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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/057,171	01/25/2002	Thomas A. Vendola	PC11014AGLK	5278

7590

04/08/2003

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EXAMINER

HUI, SAN MING R

ART UNIT

PAPER NUMBER

1617

DATE MAILED: 04/08/2003

7

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/057,171

Applicant(s)

VENDOLA, THOMAS A.

Examiner

San-ming Hui

Art Unit

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 21 January 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-38 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-38 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### **DETAILED ACTION**

Applicant's amendments filed January 21, 2003 have been entered.

The outstanding rejection under 35 USC 112, second paragraph is withdrawn in view of the amendments filed January 21, 2003.

The outstanding rejection under 35 USC 103 is withdrawn in view of the applicant's remarks that Heinemann teaching a porous tablet, which no motivation is provided by the cited prior art to further compress the porous composition of Heinemann.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 33-37 are rejected under 35 U.S.C. 102(b) as being anticipated by Hanes et al. (US Patent 5,855,913).

Hanes et al. teaches porous particulate for drug delivery (See claim 1; col. 11, line 55 – col. 15, line 42: Example 2).

Claims 33-37 are rejected under 35 U.S.C. 102(b) as being anticipated by Straub'698 (US Patent 5,853,698).

Straub'698 teaches porous pharmaceutical particles for imaging (col. 7, line 9 – col. 9, line 34).

Claims 33-37 are rejected under 35 U.S.C. 102(e) as being anticipated by Straub'300 (US Patent 6,395,300).

Straub'300 teaches porous pharmaceutical particles for drug delivery (See the abstract). Straub'300 also teaches that such particles be made to become tablet (See particularly the abstract).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-32 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Straub'300 in view of Remington (Remington's Pharmaceutical Sciences, 18<sup>th</sup> ed., 1990, pages 1633-1647), Remington is of record.

Straub'300 teaches a method of preparing porous pharmaceutical microparticles by mixing the drug with solvents and a pore forming agent to form emulsion, and then evaporate the solvent and the pore forming agent to form the microparticles (See the abstract; also col. 11, line 47 – col. 13, 46; claim 1). Straub'300 also teaches the particles of porous matrix can be formulated further into a tablet (See particularly col. 13, line 39). Straub'300 teaches that the pore forming agent as ammonium bicarbonate (See claim 7). Straub'300 also teaches the amount of the solid pore forming agent as 10 to 100% of that of the active drug (See col. 11, line 45).

Straub'300 does not teach the wet or dry granulation method being employed. Straub'300 does not expressly teach the compression of the tablet being employed. Straub'300 does not teach the employment of a compressive agent into the composition. Straub'300 does not teach the herein claimed amount for the solid volatilizable agent.

Remington teaches that wet and dry granulation method is a well-known, commonly used methods of preparation for tablets (See page 1641, col. 2 – page 1644, col. 2, last paragraph). Remington also teaches compressible sugars such as lactose, sucrose, and starch can be used for direct compression (See page 1645, col. 2, last paragraph).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ wet and dry granulation method and incorporate a compressive agent into the method of Straub'300. It would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare a tablet by further compressing the porous particles of Straub'300.

One of ordinary skill in the art would have been motivated to employ wet and dry granulation method and incorporate a compressive agent into the method of Straub'300 because the wet and dry granulation and incorporating compressive agents are well-known in the art to be useful for formulating a tablet. Employing well-known method and excipients in formulating pharmaceutical composition would be obvious as being within the purview of skilled artisan.

One of ordinary skill in the art would have been motivated to prepare a tablet by further compressing porous particles of Straub'300. Compression of particles into a tablet is a well-known method for tablet preparation. Straub'300 teaches that the porous particles therein are useful in further processing into tablets. Therefore, employing any well-known method and excipients in formulating pharmaceutical tablet such as compression and the compression aids would be obvious as being within the purview of skilled artisan. Furthermore, The optimization of result effect parameters (amount of excipients employed) is obvious as being within the skill of the artisan.

### ***Response to Arguments***

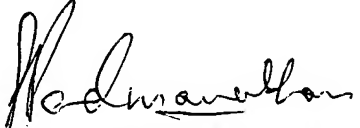
Applicant's arguments with respect to claims 1-38 have been considered but are moot in view of the new ground(s) of rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to San-ming Hui whose telephone number is (703) 305-1002. The examiner can normally be reached on Mon 9:00 to 1:00, Tu - Fri from 9:00 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, PhD., can be reached on (703) 305-1877. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

San-ming Hui  
April 3, 2003

  
SREENI PADMANABHAN  
PRIMARY EXAMINER 4/7/03